

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Stephen Solomon et al.

Application No.: 10/702,194

Filed: November 4, 2003

For: FOOD EXTRACTION APPARATUS
AND METHOD

Group Art Unit: 3761

Examiner: Keshia L. Gibson

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Applicants respectfully ask the Board to reverse the final rejections under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 112, second paragraph of claims 32-34 and the final rejection under 35 U.S.C. § 103 of claims 17, 18 and 32-34 in the above-identified application.

The Commissioner is authorized to charge any fees required in connection with this paper, including but not limited to the fee required by 37 C.F.R. § 41.20(b)(2), to Deposit Account No. 16-2500.

Real Party in Interest

The real party in interest is Aspiration Medical Technology LLC, a limited liability company registered in the state of Delaware, and the assignee of record.

Related Appeals and Interferences

There are no related Appeals or Interferences.

Status of Claims

Claims 17, 18 and 32-34 are pending. Claims 21-31 have been cancelled without prejudice. Claims 32-34 stand rejected under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 112, second paragraph. Claims 17 and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Shapiro in view of Corley, and claims 32-34 stand rejected under 35 U.S.C. § 103 as being unpatentable over Shapiro taken alone. Claims 17, 18 and 32-34 are the subject of this appeal. Claims 1-15 were previously withdrawn and claims 16 and 19 were previously cancelled.

Claims 17 and 32-34 are independent.

Status of Amendments

The claims from the Amendment dated May 10, 2006 are the ones that remain under consideration. Those claims are reproduced below in the Claims Appendix.

Summary of Claimed Subject Matter

The claimed subject matter relates generally to a method for treating obesity by removing food from a patient. In one embodiment described in paragraph 15 in the published application, a tube is inserted into a patient's upper digestive system and a pump is attached to the tube to remove the food from the patient.

More specifically, claim 17 relates to a four-step method of treating obesity. The first step is to insert a tube into a patient such that a proximal end portion of the tube is disposed in the upper digestive system of the patient and a distal end portion of the tube extends externally from the patient. (See paragraph 30 in the published application, reference nos. 1, 3, 16 and 17, in FIG. 1, and FIG. 6.) The second step is to connect a pump to the distal end portion of the tube. (See paragraphs 48-53 in the published application, reference nos. 6, 8 and 9 in FIGS. 2-5.) The third step is to control the pump to remove partially digested food from the upper digestive system of the patient through the tube. (See paragraphs 49-53 in the published application and reference nos. 6-9 and in FIG. 2-5.) The fourth step is to monitor the volume of pumped food and end the pumping when the monitored volume exceed preset parameters within a given time. (See paragraphs 54 and 55 in the published application, reference nos. 6-11 in FIGS. 2-6.)

Claim 32 relates to a related four-step method of treating obesity. The first step is to position a tube so that it passes through an obese patient's abdominal wall into the upper digestive system of the obese patient. (See paragraph 30 in the published application, reference nos. 1, 3 and 5, in FIG. 1, and FIG. 6.) The second step is to allow the obese patient to ingest food. (See paragraph 54 in the published application) The third step is to extract the food from the upper digestive system of the obese patient through the tube after the obese patient has

ingested the food. (See paragraphs 49-53 in the published application and reference nos. 6-9 and in FIG. 2-5.) The fourth step is to repeat the second and third steps until the patient is no longer obese. (See paragraphs 14 and 50-54 in the published application, reference nos. 6-9 and in FIG. 2-5.)

Claim 33 relates to a related four-step method of treating obesity. The first step is to introduce a passageway into an obese patient's upper digestive system so that the passageway passes through the obese patient's abdominal wall. (See paragraph 30 in the published application, reference nos. 1, 3 and 5, in FIG. 1, and FIG. 6.) The second step is to allow the obese patient to ingest food. (See paragraph 54 in the published application) The third step is to extract the food from the upper digestive system of the obese patient through the passageway after the obese patient has ingested the food. (See paragraphs 49-53 in the published application and reference nos. 6-9 and in FIG. 2-5.) The fourth step is to repeat the second and third steps until the patient is no longer obese. (See paragraphs 14 and 50-54 in the published application, reference nos. 6-9 and in FIG. 2-5.)

Claim 34 relates to a related three-step method of achieving weight loss in an obese person who has a passageway that passes through their abdominal wall and into their upper digestive system. The first step is to allow the obese patient to ingest food. (See paragraph 54 in the published application) The second step is to extract the food from the upper digestive system of the obese patient through the passageway after the obese patient has ingested the food. (See paragraphs 49-53 in the published application and reference nos. 6-9 and in FIG. 2-5.) The third step is to repeat the first and second steps until the patient is no longer obese. (See paragraphs 14 and 50-54 in the published application, reference nos. 6-9 and in FIG. 2-5.)

Grounds of Rejection to Be Reviewed on Appeal

- I. Whether claims 32-34 fail to comply with the written description requirement under 35 U.S.C. § 112, first paragraph.
- II. Whether claims 32-34 fail to set forth the subject matter which applicants regard as their invention under 35 U.S.C. § 112, second paragraph.
- III. Whether claims 17 and 18 are unpatentable under 35 U.S.C. § 103 over Shapiro in view of Corley, III et al.
- IV. Whether claims 32-34 are unpatentable under 35 U.S.C. § 103 over Shapiro.

Argument

I. The Rejection under 35 U.S.C. § 112, First Paragraph

Claims 32-34 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner argues, in paragraph 10 of the Office Action, that there is no support within the original disclosure for a method comprising the step of inserting a tube into an obese patient. Applicants respectfully disagree and submit that support can be found in the object of the invention section at paragraph 14 in the published application. Specifically, that portion of the published application states that “it is an object of the present invention to provide an apparatus and method for treating morbid obesity through a non-surgical approach.” The fact that the disclosed apparatus and method is intended as a treatment for obesity provides sufficient support for the tube being inserted into an obese patient. Accordingly, claims 32-34 satisfy the written description requirement under 35 U.S.C. § 112, first paragraph and Applicants ask the Board to reverse this rejection.

II. The Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 32-34 stand rejected under 35 U.S.C. § 112, second paragraph. The Examiner argues, in paragraph 12 of the Office Action, that the method steps of Shapiro are the same as those claimed in the present invention and that because the steps are the same, the results must inherently be the same. Applicants respectfully submit that the method steps in claims 32-34 are not the same as the method steps in Shapiro because those claims contain limitations that are not taught or suggested in Shapiro.

Independent claims 32-34 are being argued together as a group for purposes of this rejection because their rejection is believed improper for the same reasons. Claims 32-34 each recite a method of treating obesity or achieving weight loss in an obese patient. According to claims 32 and 33, a tube or passageway is introduced through the obese patient's abdominal wall into the upper digestive system. Next the obese patient is allowed to ingest food and then the food is extracted from the upper digestive system of the obese patient through the tube or passageway after the obese patient has ingested the food. Lastly, the steps of ingesting food and extracting the ingested food are repeated until the obese patient is no longer obese. Claim 34 is similar to claims 32 and 33 except that since the method is done in a person who already has a passageway through their abdominal wall, claim 34 does not recite the step of introducing the tube or passageway.

Applicants submit that the method steps recited above in claims 32-34 are not taught or suggested in the cited prior art. Specifically, claims 32-34 recite a method of treating obesity or of achieving weight loss in an obese person, and Shapiro does not disclose or teach treating obesity or achieving weight loss in an obese person. Instead, Shapiro discloses sham feeding as a way to mimic bulimia.

This distinction is explicitly recited in claims 32 and 33, which recite the steps of introducing a tube or passageway through an obese patient's abdominal wall, allowing the obese patient to ingest food, extracting the food from the obese patient, and repeating the steps of ingesting and extracting food until the patient is no longer obese. As stated above, claim 34 is similar to claims 32 and 33 except that claim 34 does not recite the step of introducing a tube or passageway through the obese patient's abdominal wall. Since Shapiro does not describe the steps of introducing a tube or passageway through an obese patient's abdominal wall, allowing

the obese patient to ingest food, or extracting the food from the obese patient, applicants submit that the limitations recited in the claims are not taught or suggested by Shapiro. The significance of these limitations is supported by *Perricone v. Medicis Pharmaceutical Corp.*, 77 USPQ2d 1321 (Fed. Cir. 2005), which held that limitations that relate to characteristics of the subject being treated can provide patentability, and that “new uses of old products or processes are indeed patentable subject matter.” *Id.* at 1328. (*Perricone* is discussed below in section IV.)

In addition, the “repeating” step constitutes a time-related limitation that specifies how long the previous steps must be repeated, which is another concept that is neither taught nor suggested by Shapiro. Since these steps are completely absent from Shapiro, Applicants submit that neither the steps of the methods recited in claims 32-34 nor the results obtained when those methods are performed are the same as in Shapiro. Accordingly, Applicants submit that the rejection under 35 U.S.C. § 112, second paragraph is improper and ask that the Board reverse this rejection.

III. The Rejection under 35 U.S.C. § 103 over Shapiro in View of Corley, III et al.

Claims 17 and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Shapiro in view of Corley, and the Examiner relies on Corley to satisfy the limitation “monitoring the volume of pumped food and ending the pumping when the monitored volume exceeds preset parameters within a given time.” As best understood by Applicants, the Examiner provides two bases for her rejection in paragraph 20 of the Office Action.

First the Examiner asserts that the above-quoted limitation does not provide patentability “since it is known to monitor the a [sic] pump to prevent the pump from overflowing and ending the pump when its capacity is exceeded.” Applicants submit that the Examiner’s logic is flawed

because ending pumping when a pump's capacity is exceeded is not the same as "ending the pumping when the monitored volume exceeds preset parameters within a given time," as recited in claim 17.

Next, the Examiner asserts that Corley's teaching of monitoring an amount of fluid extracted from an animal satisfies the above-quoted limitation. Applicants respectfully disagree because Corley deals with sampling digestive fluids from the rumen of an animal to monitor the animal's health. For example, Corley explains, that "A pump draws sampled fluid which collects inside the filter, to a collection vessel" (col. 4, lines 25-31). However, since the pore size of the filter is 6 μm , most particles are removed in Corley as the fluid seeps into the filter (col. 5, lines 6-7). Because Corley's system uses such a filter, it could not possibly be used to extract food from a patient, as recited in claim 17. Therefore, Applicants submit that it is impermissible to combine Shapiro with Corley because there would be no reasonable expectation of success. The Examiner has not established a prima facie case of obviousness because a reasonable expectation of success is a basic criteria of obviousness. See M.P.E.P. § 2143.

In addition, even if Corley's system could be used to extract food from a patient, Applicants submit that it would be improper to combine Corley with Shapiro because the field of Corley (i.e., monitoring the health of farm animals by sampling fluid from their rumens, as described in the Abstract and col. 1, lines 10-12) is different from the field of the present invention (i.e., achieving weight loss). Applicants submit that Corley is not in the field of their endeavor nor reasonably pertinent to the particular problem with which the invention is concerned, i.e., treating obese patients and achieving weight loss. See M.P.E.P. § 2141.01(a) .

Finally, Applicants submit that neither Shapiro nor Corley teaches or suggests the limitations recited in claim 17 of "monitoring a volume of pumped food" and "ending the

pumping when the monitored volume exceeds preset parameters within a given time.”

Applicants therefore submit that the Examiner has not made a prima facie case of obviousness because “to establish a prima facie obviousness of a claimed invention, all the claim limitation must be taught or suggested by the prior art.” M.P.E.P. § 2143.03. Applicants therefore ask that the Board reverse this rejection.

IV. The Rejection under 35 U.S.C. § 103 over Shapiro.

Claims 32-34 stand rejected under 35 U.S.C. § 103 as being unpatentable over Shapiro. The Examiner argues, in paragraph 20 of the Office Action, that (a) Shapiro teaches that the binge-purge process of bulimia is used by a person to control their weight gain and (b) that Shapiro has “correlated” the models of bulimia to obesity, and that these two factors make it obvious to modify the method of Shapiro to treat obese patients.

Applicants respectfully disagree for three reasons. First, the only link between bulimia and obesity at the cited portion of Shapiro (pp. 116-117) seems to be that they are used together in the same sentence a few times. But since nothing in Shapiro suggests that bulimia and obesity are the same thing, the fact that they appear in the same sentence does not establish that they are interchangeable. In addition, the cited portions of Shapiro do not deal with treating bulimia – they deal with modeling or “mimicking” bulimia. Thus, even if obesity and bulimia were deemed to be interchangeable, the most that one could say about Shapiro is that it suggests a way to mimic obesity, but not a way to treat obesity. Thus, no prior art has been cited that teaches or suggests extracting food from the upper digestive system of an obese patient.

Second, it would not be obvious to modify the method of Shapiro to treat obese patients because there is no suggestion or teaching in Shapiro of using any of the animal models for

treatment of eating disorders. In direct contrast, Applicants' understanding of Shapiro is that the author is critiquing the use of animal models in eating disorder research. (See page 111). This is apparent from his sarcastic remark found at page 144 in which he rhetorically asks, "[w]hat could be more farfetched than studying the peculiar and apparently culturally driven psychology and behavior of bulimia by observing the eating behavior of a rat whose stomach has a hole cut into it...?" Ultimately, the author reaches the conclusion that "animal models have contributed virtually nothing toward the effective treatment of eating disorders." (See page 210).

Accordingly, Applicants submit that it would not have been obvious to modify the method in Shapiro for the purpose of treating obese patients.

Finally, the fact that the method steps of claims 32-34 positively recite that the patient is obese is significant, and those claims are believed patentable based on the limitations "through an obese patient's abdominal wall," "allowing the obese patient to ingest food," and "extracting the food from the upper digestive system of the obese patient," in view of the Federal Circuit's decision in *Perricone v. Medicis Pharmaceutical Corp.*, 77 USPQ2d 1321 (Fed. Cir. 2005). Claim 1 of the patent at issue in *Perricone* (patent No. 5,409,693) was directed to "A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid" *Id.* at 1323-24. Although the prior art described topical application of the same fatty acid ester to skin, the Federal Circuit held that the general teaching of topical application in the prior art was not enough to anticipate a claim that explicitly recites topical application of the fatty acid ester to skin sunburn. *Id.* at 1328. Thus, in situations when a new use is positively recited in the steps of a method claim, "new uses of old products or processes are indeed patentable subject matter." *Id.*

Following the same reasoning, in order to properly reject claims 32-34, the Examiner has the burden of finding prior art where food was extracted from the upper digestive system of an obese patient, and where it is done via a tube or passageway through the obese patient's abdominal wall. Since Shapiro fails to teach or suggest "extracting the food from the upper digestive system of [an] obese patient," this limitation is not satisfied by the cited art. Accordingly, Applicants submit that claims 32-34 are not obvious in view of Shapiro and ask that the Board reverse this rejection.

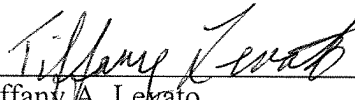
In view of the foregoing amendments and remarks, Applicant respectfully asks the Board to reverse the outstanding rejections. Applicant's undersigned attorney may be reached by telephone at (212) 969-3686 or by facsimile at (212) 969-2900. Please continue to direct all correspondence to Customer No. 21890 at the address provided below.

Respectfully submitted,

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Claims Appendix

Claim 1 (withdrawn): An apparatus comprising:

a transabdominal tube having a proximal end portion adapted to be inserted into the upper digestive system of a patient and a distal end portion adapted to extend externally from the patient; and

a pump attachable to the tube for removing partially digested food from the upper digestive system of the patient.

Claim 2 (withdrawn): The apparatus of claim 1, wherein the pump is attachable to the distal end portion of the tube.

Claim 3 (withdrawn): The apparatus of claim 1, wherein the pump is removable from the tube and comprises at least one of a cylindrical pump, a bulb pump, and a syringe.

Claim 4 (withdrawn): The apparatus of claim 3, wherein the pump is automated and the apparatus further comprises a control section to activate the pump.

Claim 5 (withdrawn): The apparatus of claim 4, wherein:

the control section comprises sensors which detect at least one of a volume of the removed food and a biochemical/nutritional status of the patient; and

the control section deactivates the pump when one of (i) the detected volume exceeds preset parameters within a given time and (ii) the detected biochemical/nutritional status exceeds preset parameters.

Claim 6 (withdrawn): The apparatus of claim 5, wherein control section transmits at least one of the detected volume and the detected biochemical/nutritional status to a health care provider.

Claim 7 (withdrawn): The apparatus of claim 6, wherein the control section records detected information.

Claim 8 (withdrawn): The apparatus of claim 3, wherein the pump is manually operable.

Claim 9 (withdrawn): The apparatus of claim 1, further comprising a bag adapted to be attached to the pump; and wherein the removed food is pumped into the bag.

Claim 10 (withdrawn): The apparatus of claim 1, further comprising a cap for plugging the distal end portion of the tube when the pump is not attached to the tube.

Claim 11 (withdrawn): The apparatus of claim 1, further comprising an anchor to hold the tube in the upper digestive system of the patient.

Claim 12 (withdrawn): The apparatus of claim 11, wherein the anchor comprises a balloon anchor coupled to the tube and adapted to be anchored in the upper digestive system of the patient.

Claim 13 (withdrawn): The apparatus of claim 12, wherein the balloon anchor is adapted to be variably inflated so as to selectively fill a desired portion of the stomach of the patient.

Claim 14 (withdrawn): The apparatus of claim 12, wherein the tube includes an inflation lumen coupled to said balloon for communicating with the interior of the balloon.

Claim 15 (withdrawn): The apparatus of claim 1, wherein the tube includes a one way valve adapted to prevent the partially digested food from unintentionally escaping from the tube; and wherein the one way valve is adapted to be opened when the pump is attached to the tube.

Claim 16 (cancelled).

Claim 17 (previously presented): A method comprising:

inserting a tube into a patient such that a proximal end portion of the tube is disposed in the upper digestive system of the patient and a distal end portion of the tube extends externally from the patient;

connecting a pump to the distal end portion of the tube;

controlling the pump to remove partially digested food from the upper digestive system of the patient through the tube

monitoring a volume of the pumped food;

ending the pumping when the monitored volume exceeds preset parameters within a given time.

Claim 18 (previously presented): The method of claim 17, further comprising transmitting the volume of the pumped food to a health care provider.

Claim 19 (cancelled).

Claim 20 (withdrawn): An apparatus comprising:

a first tube adapted to be inserted into the upper digestive system of a patient;

a second tube adapted to be inserted into the lower digestive system of the patient;
wherein the first and second tubes are adapted to be connected in a subcutaneous tunnel; and
wherein partially digested food is transported through the first tube and the second tube from the upper digestive system to the lower digestive system of the patient.

Claims 21-31 (cancelled).

Claim 32 (previously presented): A method of treating obesity comprising the steps of:

(a) positioning a tube that passes through an obese patient's abdominal wall into an upper digestive system of the obese patient;

(b) allowing the obese patient to ingest food;

(c) extracting the food from the upper digestive system of the obese patient through the tube after the obese patient has ingested the food; and

(d) repeating steps (b) and (c) until the patient is no longer obese,

wherein the food that has been extracted in step (c) is not reintroduced into the obese patient.

Claim 33 (previously presented): A method of treating obesity comprising the steps of:

(a) introducing a passageway into an obese patient's upper digestive system such that the passageway passes through the obese patient's abdominal wall;

(b) allowing the obese patient to ingest food;

(c) extracting the food from the upper digestive system of the obese patient through the passageway after the obese patient has ingested the food; and

(d) repeating steps (b) and (c) until the patient is no longer obese,

wherein the food that has been extracted in step (c) is not reintroduced into the obese patient.

Claim 34 (previously presented): A method of achieving weight loss in an obese person having a passageway into the obese person's upper digestive system that passes through the obese person's abdominal wall, the method comprising the steps of:

(a) ingesting food;

(b) extracting the food from the upper digestive system of the obese person through the passageway after the food has been ingested; and

(c) repeating steps (a) and (b) until the person is no longer obese,

wherein the food that has been extracted in step (b) is not reintroduced into the obese person.

Evidence Appendix

– none –

Related Proceedings Appendix

— none —